

**Amendment #1
to RFP-NIH-NIAID-DMID-02-26**

"Production and Testing of Vaccines Against Anthrax"

Amendment to Solicitation No.:	<u>NIH-NIAID-DMID-02-26</u>
Amendment No.:	1
Amendment Date:	May 28, 2002
RFP Issue Date:	April 22, 2002
Issued By:	Jacqueline C. Holden Contracting Officer NIH/NIAID Contract Management Branch 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
Point of Contact:	Phil Hastings, Contracting Officer ph23k@nih.gov
Name and Address of Offeror:	To All Offerors

The above numbered solicitation is amended as set forth below:

The 4th Paragraph of the BACKGROUND is modified to read as follows:

This solicitation is a request for proposals to develop, manufacture, characterize, and evaluate a pilot lot of *B. anthracis* recombinant protective antigen (rPA) vaccine and to supply the appropriate CMC information to support use of this product as an Investigations New Drug (IND) with the FDA. More than one award may be made for Part A, but only one candidate vaccine from Part A is expected to be selected for Part B. Progress will be measured against specific milestones that are listed in the Statement of Work below, and contract support for candidate vaccines that lag in meeting the milestones will be discontinued.

The STATEMENT OF WORK is modified to read as follows:

ITEM #1 is deleted in its entirety and replaced with the following:

Using intellectual property to which the company has unencumbered access and technology known to be acceptable in the production of vaccines licensed for use in the U.S., develop a prototype recombinant *Bacillus anthracis* Protective Antigen (PA) vaccine that will protect against lethal challenge with *B. anthracis* spores in at least two appropriate animal models of inhalation anthrax as soon as possible after the administration of not more than 3 immunizing doses compatible with post-exposure immunization. (See Note #1 to Offeror)

ITEM #6, Milestone 5 is revised to incorporate both Notes #5 and #6 to Offeror.

MEETINGS AND CONFERENCES - is deleted in its entirety and replaced with the following:

The Contractor shall participate in regular meetings to coordinate and direct the contract effort as directed by the Project Officer. Such meetings may include, but are not limited to, meetings of all contractors to discuss clinical protocol design; and meetings with individual contractors and other PHS officials to discuss the technical,

regulatory and ethical aspects of the program. (See Note #7 to the Offeror)

NOTES TO OFFERORS – Current NOTE #6 (refers to Meetings and Conferences) is renumbered as NOTE #7 and the following new NOTE #6 (refers to Milestone #5 and the evaluation process for the successful contractor for Part B - Option) is added to read as follows:

Note #6 TO OFFEROR (refers to Milestone #5 and the evaluation process for the successful contractor for Part B – Option) It is the intention of the NIAID to convene an independent Blue Ribbon Panel composed of *ad hoc* experts and Government personnel, that will advise the Institute on the selection of the contractor who will be performing Part B of this Statement of Work. This Panel will base its evaluation on all items delivered under this contract as specified in the Statement of Work and the Reporting Requirements included under Section A of this RFP, and any other materials the contractor may submit to assist in the evaluation process. Additionally, other information, including but not limited to evidence of compliance with cGMP requirements, or documentation necessary for IND preparation, received from other Government sources (i.e., FDA, CDC, etc.) will also be considered by the Panel in its evaluation. This evaluation is scheduled to take place shortly after month 12 of the contract, however, the Government reserves the right to convene the Blue Ribbon Panel and review information that substantially accelerates the ability of the Government to exercise Optional Part B of the Statement of Work.

SECTION I, CONTRACT CLAUSES, is modified to add the following:

FAR 52.227-16, Additional Data Requirements (JUNE 1987)

SECTION M - EVALUATION FACTORS FOR AWARD - is modified to read as follows:

Item #1 is deleted in its entirety and replaced with the following:

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost/price, and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, cost/price, and SDB participation are also important to the overall contract award decision. Technical evaluation factors however are significantly more important than cost or price and SDB participation factors. In any case, the Government reserves the right to make an award(s) to that offeror(s) whose proposal provides the best overall value to the Government based on the evaluation factors set forth in this Section.

Item #5, Past Performance Factor, is deleted in its entirety and all subsequent paragraphs are re-numbered.

Renumbered Item #6, Technical Evaluation Criteria, paragraph #1 is deleted in its entirety and replaced with the following:

Proposals submitted in response to this RFP will be evaluated based on the following technical factors that are listed and weighted in order of their relative importance in meeting the objective of the RFP as described in the Background to the Statement of Work. Proposals will be judged solely on the written material provided by the offeror.

Except as provided herein, all terms and conditions of the RFP document NIH-NIAID-DMID 02-26 remain unchanged and in full force and effect.

The hour and date specified for receipt of offers is **NOT** extended.

Offerors must acknowledge receipt of this Amendment #1, by the following method:

- By acknowledging receipt of the amendment on each copy of the offer submitted.

Failure to receive your acknowledgment of this amendment may result in the rejection of your offer.

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